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10/521,730	01/20/2005	Robert John Noel	MCA-609 US	2258

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MILLIPORE CORPORATION
290 CONCORD ROAD
BILLERICA, MA 01821

EXAMINER	
SAUNDERS, DAVID A	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,730	NOEL, ROBERT JOHN	
	Examiner	Art Unit	
	David A. Saunders	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

AMENDMENT ENTRY

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/18/08 has been entered. Following entry of the Amendment of 6/18/08, claims 1-3 And 5-20 are pending and are under examination.

CORRECTIONS REGARDING PREVIOUS OFFICE ACTION

The following corrections pertain to the previous Office action:

At page 3, 3rd line from bottom, "1-2, 4, 6 and 9-11" should have read as –1-2, 6 and 9-11--.

OBJECTIONS/REJCTIONS OVERCOME

The amendment has overcome previously stated issues as follows:

The rejection of claim 1 under 35 USC 112, 2nd paragraph regarding what the added ionic component competes with.

The rejection of claim 5 under 35 USC 112, 2nd paragraph regarding the "two ionic components".

The rejection of claims 10-11 under 35 USC 112, 1st paragraph for reciting "about".

NEW OBJECTIONS TO CLAIMS

Claim(s) 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The recitation of "protein" in claim 6 does not further limit claim 1. Applicant is required to cancel the claim and to render further dependent claims 7-8 dependent from claim 1.

NEW REJECTIONS UNDER 112, SECOND PARAGRAPH

Claims 1-3 and 5-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 variously recite the phrases "selected ionic protein component" and "selected ionic component". Consistent recitation of "selected ionic protein component" is required.

In claims 1, 12 and 15 it is unclear what is meant by the phrase "in the absence of an added salt that binds the ionic adsorbent". See rejection under 112, first para. below, for an explanation of why applicant has not adequately described/disclosed what "in the absence of an added salt" means.

NEW REJECTIONS UNDER 112, FIRST PARAGRAPH

Claims 1-3 and 5-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's original disclosure has failed to adequately describe what is meant by the phrase "in the absence of an added salt that binds the ionic adsorbent".

In its literal sense one could only interpret "in the absence of an added salt that binds the ionic adsorbent" to mean that absolutely no added salt is present in step a) of claims 1, 12 and 15. However when one reads the disclosure, it is clear that the "sample" is not devoid of "added salt". Note that Example 1 has a "sample" consisting of IgG and protein A in a buffer of pH 4.0 to 4.5. The teachings therein fail to state what the composition or concentration of the buffer might be. Whatever the composition and concentration thereof, there must inherently be some positive ions that would bind to a cation exchange matrix/adsorbent. That is, if applicant had used an acetate buffer, there would need to be both HAc and NaAc (or KAc) present to provide for any buffering

capacity. This is necessarily true for any kind of buffer, other than an acetate buffer. Thus the "sample" of Example 1 must have inherently had Na+ (or K+) ions added thereto, and these positive ions would certainly have been able to bind to the SP cationic groups of the matrix/adsorbent. Applicant, however, has not provided the composition or concentration of the buffer; therefore, one has no idea what applicant might have contemplated as being the permissible range and/or upper limit of concentration for a positive charged ion that can bind to the matrix/adsorbent.

Likewise, it is to be noted that applicant has contemplated separation of biomolecules from complex mixtures, such as blood and cell culture broths (e.g. claim 20). It is necessarily true that whole blood, or plasma derived therefrom, as well as a mammalian cell culture medium, would contain positive ions such as Na+ and K+. Blood has a tonicity equal to ca. 0.15 M NaCl, and any mammalian cell culture medium would have a similar tonicity. Therefore, for these samples, there are inherently positive ions would certainly be able to bind to cationic groups of any cation exchanging matrix/adsorbent. In this case, the examiner grants that there is an "absence of an added salt"; however since salt is inherently present, then one can contemplate that applicant's invention would also be operative if a man-made "sample" also contains an "added salt" -- e.g. as in the case in which a protein precipitate is redissolved in a buffer, in the case in which a protein has been eluted from a Protein A matrix.

Since applicant has not adequately described what "in the absence of an added salt that binds the ionic adsorbent" means in actual quantitative terms, one of skill cannot envision what kind of "sample" is or is not within the scope of the invention. For this reason, the examiner shall most certainly consider it proper to cite any reference which teaches a buffered sample, irrespective of the composition or concentration of the buffer, because one cannot possibly determine what applicant has described as being his invention.

Claims 1-3 and 5-20 are rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor has not been disclosed. Evidence of concealment of the best mode is based upon the fact that Applicant has not provided

the composition or concentration of the buffer used in Example 1; therefore, one has no idea what applicant might have contemplated as being the permissible range and/or upper limit of concentration for a positive charged ion that can bind to the matrix/adsorbent.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 20 contains new matter.

Specifically, claim 20 does not specify whether it is the "protein A" or the "immunoglobulin" biomolecule that is the one which is the "selected ionic biomolecule" of base claim 15. On the other hand, the original specification and original claim 8 only present the embodiment in which protein A is other than the "selected biomolecule". New claim 20 thus improperly encompasses more embodiments than are supported by the original disclosure.

Claims 19-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 20 has not been enabled such that "only the selected ionic polymeric compound is bound to the ionic adsorbent" or "only the selected ionic biomolecule is bound to the ionic adsorbent" (e.g. the immunoglobulin that binds to the ionic adsorbent), for the case in which "only" is to be interpreted strictly. Note that the single case in which applicant exemplifies a model sample containing only previously purified IgG, protein A and buffer, the binding fraction that was subsequently eluted contained "98% IgG and 2% protein A" (Example 1). Thus the binding of "only the selected ionic polymeric compound" or "only the selected ionic biomolecule" has not been

demonstrated by applicant. It is well know in the art that obtaining ion-exchange chromatographic fractions generally involve an enrichment of a "selected ionic polymeric compound" or of a "the selected ionic biomolecule", but not an exclusive purification thereof; therefore, one would be required to conduct undue experimentation in order to separate IgG and protein A, as in claim 20, if "only" is to be interpreted strictly. This position of the Office can be even more forcefully stated for the case in which one has a "real world" sample from a manufacturing process, rather than a model sample containing only previously purified IgG, protein A and buffer; that is, an eluate of IgG from a protein A column would be expected to contain leached protein A and trace amounts of other proteins. Also numerous protein impurities, other than the "selected' ionic biomolecule" would be present in a complex sample, such as blood, plasma/serum or culture fluid; for this reason, claim 19 is also rejected.

MAINTAINED RJECTION(S) UNDER 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 6 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al (cited on PTO-892 of 5/14/07).

The rejection of Claims 1-2, 6 and 9 was explained in the action of 5/14/07. The rejection of claims 10-11 was explained in the action of 2/13/08.

Applicant has urged that the reference cannot be applied, because Wu et al did not bind the ionic component (e.g. lysozyme) to the cation-exchange adsorbent "in the absence of an additional salt that binds with the adsorbent" (wherein the added second ionic component would be, for example a Na+ salt). Applicant has urged that the examiner's interpretation of the reference, as set forth in section 1) of page 4 of the Office action mailed 2/13/08, is improper, because in the reference "Fig. 2 apparently includes the use of additional salt component (*see* page 8, col. 2)."

The Office will maintain the rejection on the basis that recitation of "in the absence of an additional salt that binds with the adsorbent" can be interpreted in various ways. The examiner concurs that Fig. 2 of Wu et al was obtained under conditions in which the salt of Buffer A was present; that is, 0.01 M sodium phosphate (pH 6.0) was present (see para. spanning pp 8-9). However, Buffer B was absent; that is, 0.01 M sodium phos- 0.2 M sodium sulfate (pH 6.0) was not present. Thus, in the presence of only Buffer A and no Buffer B, 0.01 sodium phosphate was present, but 0.2 M sodium sulfate was absent. If one considers that the 0.2 M sodium sulfate is "an additional salt that binds with the ionic adsorbent" then this "additional salt" is absent in the binding conditions for lysozyme in Fig. 2 of Wu et al. Not that the recitation in claim 1 of "in the absence of an additional salt" merely requires that a single additional salt, in this case sodium sulfate, be absent; this recitation in claim 1 does not rule out the presence of second salt, such as the 0.01 M sodium phosphate of Wu et al.

Furthermore, the Office considers that salt from a buffer can be present in/added to the sample, since applicant's own teachings in Example 1 include the addition of a buffer to the sample.

Applicant has also urged that the examiner's arguments set forth in section 2) at page 5 of the action mailed 2/13/08 are erroneous because the applicant has the right to claim by way of a negative limitation. The examiner concurs that applicant has this right; however, the negative limitation of "having a charge density that selectively binds the selected ionic component in the absence of an additional salt that binds with the adsorbent" can be interpreted in various ways. It can be interpreted as limiting the method, or it can be interpreted as limiting the nature of the adsorbent – i.e. as

describing how the adsorbent would operate under the conditions in which no additional salt is present. The examiner is interpreting the negative limitation in the latter manner; thus an added salt can be present, and the negative limitation merely describes how the adsorbent would have otherwise operated (this is properly taken to be a description of the adsorbent of Wu et al, since their 75 umol/ml is within the range contemplated by applicant, as being thus operative). Applicant's amendment to claim 1 does not rule out this interpretation of step a) of claim 1, because nothing in step a) says that there actually is an "absence of an additional salt" during the "contacting". Applicant may consider that the recitation of "using an adsorbent in the absence of an additional salt", as in the preamble", does rule out the actual presence of an additional salt; however, the Office need not give weight to the preamble, if there is no obligatory nexus between what is recited in the preamble and in the body of the claim.

Applicant's arguments filed 6/18/08 have been fully considered but they are not persuasive for the above reasons.

NEW REJECTION(S) UNDER 35 USC 102

Claims 12 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Scholz et al (cited on PTO-1449 of 1/20/05).

The Scholz et al reference was cited in the rejection of 5/14/07. Due to applicant's newly presented claims 12-20, which recite no quantitative limitation upon the ligand density, this reference is again applied.

Scholz et al show that immunoglobulin protein from human serum can be adsorbed to a thiophilic adsorbent, which has a binding "ligand based on mercaptonicotinic acid, containing a carboxylic group". See last sentence of abstract, Table 3, and the para. spanning pp 195-196, with respect to teachings of the thiophilic ligand, "Nic-S-Sulphone". This adsorption of immunoglobulin can occur in both a salt-promoted and a salt-independent manner. See sentence spanning pp 195-196.

Claims 12 and 15 are anticipated for the embodiment of Scholz et al in which the adsorption of immunoglobulin occurs in a salt-independent manner. This rejection is

based on the fact that claim 1 is vague and indefinite as to what is meant by the phrase "in the absence of an added salt that binds the ionic adsorbent" (112, 2nd supra), and the fact that it is not clear how this phrase relates to the teachings of the specification (112, 1st supra). In this particular rejection, the examiner interprets the phrase "in the absence of an added salt that binds the ionic adsorbent" as encompassing, at the least, the possible presence of an added salt that may be present in a buffering composition in or added to the sample – e.g. the 25 mM sodium phosphate, pH 7.4 buffer in the case of salt free adsorption (see p 192, col. 1).

It is further noted that the "ligand based on mercaptonicotinic acid, containing a carboxylic group" has a carboxylic group that is ionized. See para. spanning pp 195-196. Thus adsorbent of Scholz et al is an "ionic adsorbent" as required by claims 12 and 15. The fact Scholz et al may consider that ionic binding is not the most prominent factor in the adsorption process (para. spanning pgs 195-196) does not detract from anticipation. That is, the adsorbent can be properly characterized as having an "ionic" group, even if the binding of immunoglobulin may be "independent of the ionic interaction of the dissociated carboxylic acid residue" (p 196, col. 1).

It is further to be noted that the examiner interprets the phrases "only the selected ionic polymeric compound" or "only the selected ionic biomolecule" (i.e. the immunoglobulin that binds to the ionic adsorbent) liberally, so that there can also be other biopolymers/biomolecules present. Note that where applicant exemplifies a model sample containing only previously purified IgG, protein A and buffer, the binding fraction that was subsequently eluted contained "98% IgG and 2% protein A" (see Example 1).

Due to the fact that human serum would contain numerous proteins, other than IgG, which would not be bound/adsorbed in the method of Scholz et al, instant claims 12 and 15 are anticipated. Regarding the limitation in claims 12 and 15 concerning "charge density", this is anticipated, since there is no quantitative value recited concerning the "charge density".

Claim 16 is anticipated since Schloz et al eluted (desorbed) IgG with NaOH. See Table 3.

It is to be noted that the examiner has purposely not rejected instant claims 14 and 17, since the ionized carboxyl group on the Nic-S-Sulphone adsorbent is not considered by Scholz et al to be a cation exchanger. See their teachings that the binding of immunoglobulin is "independent of the ionic interaction of the dissociated carboxylic acid residue" (p 196, col. 1).

Claims 1-2, 5-7, 9-12, 1417 and 19 are rejected under 35 U.S.C. 102(a), (b) or (e) as being anticipated by Lihme et al (US 6,498,236 or WO 98/08603, cited on attached PTO-892).

The US and foreign references have the same disclosure. The rejection is based upon 102 (a)/(e) for the former and under 102 (b) for the latter. For convenience the examiner will refer to the US document by col. and line number.

Lihme et al teach chromatographic adsorbents/matrices which have a negative charge on their surface, due to the presence of a COOH group attached to an aromatic ring. This group would be ionized at the taught pK range values for the COOH group and the taught pH ranges values for adsorption (e.g. see col. 8, lines 46-65 and col. 15, lines 25-41). For the exemplified 2-mercaptobenzoic acid (2-MBA), the pH values at which binding of immunoglobulins are in the acid range, where the COOH group would be ionized (e.g. col. 31, lines 27-59). For the exemplified 2-amino-benzoic acid (4-ABA), the pH values at which binding of immunoglobulins are in the acid range, where the COOH group would be ionized (e.g. col. 35, lines 1-52). For the exemplified 2-mercapto-nicotinic acid, the pH values at which binding of immunoglobulins are in the acid range, where the COOH group would be ionized (e.g. col. 36, lines 1-50). The operative ligand densities are taught at col. 18, lines 17-32; col. 30, lines 29-34; col. 34, lines 62-67; col. 35, lines 62-65

The exemplified separations of IgG from an "Artificial Culture Supernatant" (col. 30, lines 30+) and from sera (col. 38, lines 9+) most certainly show the separation of a "selected" IgG from "additional ionic components", other "ionic polymeric compounds" (e.g. in the fetal calf serum of the "Artificial Culture Supernatant"), or a second "ionic biomolecule".

From the above instant claims 1-2, 5-7, 10-12, 14-15 and 17 are anticipated.

For claims 9 and 16, note that Lihme et al elute the adsorbed IgG (e.g. col. 4, lines 30-33; col. 7, lines 19-47; col. 30, lines 56-61; col. 32, lines 19-61; col. 35, lines 31-53).

Regarding claim 19, it is taken that the exemplification of purification of IgG from an Artificial Culture Supernatant" would permit one of skill to immediately envision "cell culture broth" sample. Also note Lihme et al at col. 9, lines 18-26.

It is noted that Lihme et al add a buffer to the "Artificial Culture Supernatant" samples, prior to contacting these samples with the adsorbent/matrix (e.g. col. 29, lines 34-38). Such addition of buffer would add salt to the sample; however, the Office considers that such addition is permitted, since applicant's own teachings in Example 1 include the addition of a buffer to the sample (see 112, first rejections supra).

Claims 12 and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hahn et al (Jour. Chromat. A., 795, 277-287, 1998, cited on attached PTO-892).

Hahn et al show a sample of bovine whey. The whey is prepared by addition of HCL to milk, in order to precipitate casein, which is then removed by centrifugation. The thus obtained whey was diluted with water to a conductivity of 2.7 mS/cm. The Office sees such preparation of whey as indistinguishable from that exemplified by applicant (example 2). See Hahn et al at para. spanning pp 278-279. Thus it is properly considered that no salt was added that would bind to the ionic adsorbent.

The thus prepared whey is then contacted with one of various cation-exchange resins, including S-Sepharose FF (p 278, col. 2) under conditions such that IgG bound to the adsorbent and alpha-lactalbumin passes through the column (para. spanning pp 280-281). Thus there is a separation "of a selected ionic polymeric compound from a sample having at least two ionic polymeric compounds" or of "of a selected ionic biomolecule from a sample having at least two ionic biomolecules". From the above, instant claims 12, 14-15 and 17 are anticipated.

Regarding claim 16, Hahn et al then elute the bound IgG (see pp 281-282).

NEW REJECTION(S) UNDER 35 USC 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5-6, 9-12 and 15-16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Reithorst et al (4,883,598, cited on PTO-892).

Reithorst et al teach anion exchange matrices/adsorbents that have a ligand density that is "preferably higher than 30 umoles/ml, more preferably higher than 50 umoles/ml and most preferably 60-100 umoles/ml of swollen gel" (col. 8, lines 24-28). They disclose numerous matrices/adsorbents that have a ligand density in the range from 40-80 umoles/ml (Tables 1-9), which are within applicant's recited ranges of "10 to 100", "20 to 90" and "30 to 80 umol/ml". These matrices are used for the selective adsorption and elution of various blood coagulation factors, such as Factor VIII and vVF (col. 6, lines 26-34; col. 9, lines 27-45). These are isolated from plasma samples, which would contain some low concentration of a salt, due to the addition of an anti-coagulant (e.g. sodium citrate). These samples also contain salt due to the presence of an acetate/lysine buffer. See col. 15, line 40-col. 16, line 15. The Office considers that such addition of anticoagulant/buffer salt is permitted, since applicant's own teachings in Example 1 include the addition of buffer salt to the sample.

From the above, instant claims 1, 5-6, 9-12 and 15-16 are anticipated or obvious. The examiner considers that the claims are anticipated; however, an obviousness rejection is made in the alternative (e.g. in the event that applicant should argue the limits of the preferred ranges taught by Reithorst et al.

Claims 1-3, 5-7, 9-10 and 12-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Graf et al, Bioseparation, 4, 7-20, 1994, cited on PTO-892).

Graf et al teach various ion exchange matrices/adsorbents for the separation of a monoclonal antibody from an animal cell culture fluid. The ueq/ml values given in Table 1 correspond to the umol/ml values recited in the instant claims. Therein DEAE Fractogel S has a binding capacity of 100 ueq/ml (upper end of range recited in instant claim 1), DEAE Sepherodex M has a binding capacity of 90 ueq/ml (upper end of range recited in instant claim 10), and SP Sepherodex M has a binding capacity of 100 ueq/ml (upper end of range recited in instant claim 1). The majority of the monoclonal antibody present in the animal cell culture fluid sample binds to the exemplified columns, and "most of the contaminant proteins are removed in the flow through fraction" (p 12, col. 2; p 18, col. 2). Thus there is selective binding of monoclonal antibody to the matrices/adsorbents.

From the above, instant claims 1, 5-7, 10, 12, 15 and 19 are anticipated or obvious.

Regarding dependent claims 2-3, 13-14 and 17-18, the SP Sepherodex M matrix (Table 1) is a cation exchanger having sulphopropyl groups.

Regarding dependent claims 9 and 16, Graf et al elute the adsorbed antibody (p 12, col. 1-2; p 17, col. 1-2).

The examiner considers that the claims are anticipated; however, an obviousness rejection is made in the alternative (e.g. in the event that applicant should argue the limits of the recited charge density ranges in relation to the ueq/ml values taught by Graf et al).

CONTACTS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 9/8/08 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644